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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,416	07/27/2001	Yukio Yamori	SAEGU85.001A	1599

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EXAMINER

Zucker, Paul A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,416

Applicant(s)

YAMORI ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 26-29 is/are allowed.
- 6) ☒ Claim(s) 11 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 27 September 2004.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Applicant's cancellation of claims 1-3 and 7-10 is acknowledged.
4. Claims 11 and 19-29 are pending.
5. The rejection under 35 USC § 102 set forth in paragraph 7 of the previous Office Action mailed 14 May 2004 is withdrawn in response to Applicants' amendment.
6. The rejection under 35 USC § 103 set forth in paragraph 8 of the previous Office Action mailed 14 May 2004 is withdrawn as moot in view of Applicants' cancellation of all relevant claims.
7. Claims 11 and 20-25 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani et al (Biochemical and Biophysical research Communications 1998, 253, pages 859-863) in view of Caspar et al (WO 00/38620-A2 07-2000) and further in view of CN1127070 (07-1996, provided by Applicants).

Instantly claimed are food and pharmaceutical compositions comprising stilbene derivatives and methods for their use in treating and preventing the loss of bone due to osteoporosis and periodontal disease.

Mizutani teaches (Page 859, left column, first two sentences after abstract) that osteoporosis associated with estrogen deficiency after menopause is the most common cause of age related bone loss. Mizutani further teaches (Page 860, FIG.2,

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bottom right) the effect on ALP (Alkaline Phosphatase) activity of treatment of osteoblastic (bone forming) MC3T3-E1 cells with resveratrol (3, 4', 5-trihydroxystilbene, corresponding to instant formula (I)). Mizutani further teaches (Page 859, bottom right, last sentence) pharmaceutical compositions comprising 0.1% BSA, vehicle and/or varying amounts of resveratrol. Mizutani further specifically teaches (Page 862, left column, last sentence) using resveratrol for the treatment of osteoporosis. Mizutani teaches (Page 859, right column, lines 10-13) that resveratrol (3, 4', 5-trihydroxystilbene, corresponding to instant formula (I)) is derived from grape cultivars (plants of the vitaceae family)

The difference between Mizutani and the instant invention is that Mizutani's teaching is limited to treatment of bone loss due to menopause while treatment of periodontal disease (alveolar bone loss) and use of resveratrol in foods is also instantly claimed.

Caspar, however, teaches (Page 2, line 12 – page 3, line 3) the use of resveratrol for the treatment of periodontal disease. Caspar further teaches (Page 5, line 3-page 8, line 9) pharmaceutical compositions comprising resveratrol. Caspar teaches (Page 5, line 15-19) rinses (mouthwash), sprays, pastes and gels as dosage forms as well.

The difference between the combined teachings of Mizutani and Caspar and the instant invention is that neither Mizutani or Caspar teach the use of resveratrol in foods is also instantly claimed. Caspar is silent with respect to employing resveratrol in food compositions.

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CN1127070, however, teaches (Abstract, lines 5 and 7-10) a composition in the form of food product (milk powder) comprising resveratrol (3, 4',5-trihydroxystilbene, corresponding to instant formula (I)). CN1127070 further teaches (Abstract, lines 7-10) is use in the treatment and prevention of coronary disease and osteoporosis.

The motivation would have been to incorporate the bone loss treatment disclosed by Mizutani along with the teachings of CN1127070 to turn compositions for the treatment of menopausal and alveolar bone loss into food products that would present a more attractive form of administration of the compositions and would lead to better patient compliance. There would have been a reasonable expectation for success would all limitations of the invention are taught by the references and all are directed to use of resveratrol.

Thus the instantly claimed compositions would have been obvious to one of ordinary skill in the art.

Examiner's Response to Applicants' Remarks with regard to this Rejection

8. Applicants have argued that Mizutani, Caspar and CN1127070 would not lead one of ordinary skill in the art to expect increases in bone breaking load and strength. Initially the Examiner agreed with Applicants. Upon further reconsideration, however, the Examiner disagrees with Applicants. Increases in bone breaking load and strength would be expected to be seen in any successful for method for the treatment of osteoporosis. These limitations are therefore simply functional descriptions of effective treatments of osteoporosis and bone resorption.

Applicant's arguments filed 27 September 2004 have been fully considered but they are not persuasive for the reasons presented above.

Allowable Subject Matter

9. Claims 19 and 26-29 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The instantly claimed method for the prevention of cerebral apoplexy is neither disclosed nor fairly suggest by Ruf et al (Arteriosclerosis, Thrombosis and Vascular Biology, Platelet Rebound Effect of Alcohol Withdrawal and Wine Drinking in Rats. Relation to Tannins and Lipid Peroxidation, 1995, 156(1), pages 140-144) the closest prior art. As Applicants point out (Remarks, page 6 2nd full paragraph) Ruf teaches away from the use of resveratrol in the absence of alcohol (ethanol) for the inhibition of platelet aggregation. The instantly claimed method which excludes the use of alcohol is therefore patentable over the teachings of Ruf.

Conclusion

10. Claims 11 and 19-29 are pending. Claims 11 and 20-25 are finally rejected. Claims 19 and 26-29 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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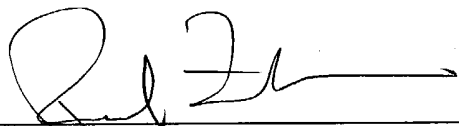
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Paul Zucker', written over a horizontal line.

Paul A. Zucker, Ph. D.
Patent Examiner
Technology Center 1600